

<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371</b>		ATTORNEY'S DOCKET NUMBER 022205-000320US  U.S. APPLICATION NO. (If known, see 37 CFR 1.5) To Be Assigned <b>200507658</b>
INTERNATIONAL APPLICATION NO. PCT/US2004/027156	INTERNATIONAL FILING DATE 18 August 2004	PRIORITY DATE CLAIMED 21 August 2003
TITLE OF INVENTION <b>COMPOSITIONS FOR DELIVERING 5-HT AGONISTS ACROSS THE ORAL MUCOSA AND METHODS OF USE THEREOF</b>		
APPLICANT(S) FOR DO/EO/US <b>SINGH, Nikhilesh N.</b>		

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ has been communicated by the International Bureau.
  - c. ☒ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☐ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

**Items 11 to 20 below concern document(s) or information included:**

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A preliminary amendment.
14. ☒ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 – 1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) <b>10/567658</b> <small>To Be Assigned</small>		INTERNATIONAL APPLICATION NO. PCT/US2004/027156		ATTORNEY'S DOCKET NUMBER 022205-000320US	
20. Other items or information: <b>Express Mail Label No. EV 338 460 177 US, mailed on February 8, 2006</b> 1) International Publication No. WO 2005/018565 A3 2) International Publication No. WO 2005/018565 A2 3) International Search Report and the Written Opinion 4) Copy of correspondence dated 31 January 2005 to WIPO 5) PCT Forms: PCT/IB/301; PCT/IB/304; PCT/IB/308; PCT/IB/318; PCT/IB/345; PCT/RO/111					
The following fees have been submitted				<b>CALCULATIONS    PTO USE ONLY</b>	
21. <input checked="" type="checkbox"/> Basic national fee (37 CFR 1.492(a)) ..... \$300				\$ 300	
22. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c))					
If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0				\$ 200	
All other situations ..... \$200					
23. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b))					
If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0					
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority ..... \$100					
International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB ..... \$400				\$100	
All other situations ..... \$500					
<b>TOTAL OF 21, 22 and 23 =</b>				\$ 600	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
73					
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	- 20		x \$ 50	\$	
Independent claims	- 3 =		x \$200	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360	\$	
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$600	
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.					
<b>SUBTOTAL =</b>				\$ 300	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				+	\$
<b>TOTAL NATIONAL FEE =</b>				\$ 300	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				+	\$
<b>TOTAL FEES ENCLOSED =</b>				\$ 300	
				Amount to be refunded:	\$
				Amount to be charged:	\$ 300

**10/567658****IAP20 Rec'd PCT/PTO 08 FEB 2006**

- a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 20-1430 in the amount of \$ 300 to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 20-1430. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

**NOTE:** Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

William B. Kezer  
TOWNSEND AND TOWNSEND AND CREW LLP  
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SIGNATURE

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REGISTRATION NUMBER

60698284v1

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10/567658

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31 January 2005

**VIA FACSIMILE TO 011.41.22.338.7010**  
**CONFIRMATION SENT VIA FEDEX**

Officer Arounni Wetzler  
The International Bureau of WIPO  
34 chemin des Colombettes  
1211 Geneva 20  
SWITZERLAND

Re: International Application No.: PCT/US2004/027156  
Title: COMPOSITIONS FOR DELIVERING 5-HT AGONISTS ACROSS THE ORAL  
MUCOSA AND METHODS OF USE THEREOF  
Applicant: Transoral Pharmaceuticals, Inc.  
International filing date: 18 August 2004  
Our File No.: 22205-3-2PC

Dear Officer Wetzler

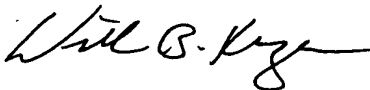
We have received the PCT/IB/301 form for the above-referenced application. However, please note that the form has 10 August 2004 as the International Filing Date. The correct International Filing Date for this application is **18 August 2004**. I have enclosed a copy of the PCT/RO/105 Notification of The International Application Number and of The International Filing Date sent to us on 27 September 2004 from the Receiving Office.

Please send us a PCT/IB/301 form with the corrected International Filing Date.

Thank you for your attention to this matter.

Respectfully submitted,

TOWNSEND and TOWNSEND and CREW LLP



William B. Kezer  
Reg. No. 37,369

WBK/m6m

Enclosure

60410216v1